

# Clinical Research Reimbursement: What You Need to Know to Plan and Execute Trials Without Creating Legal Issues

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# Laws and Regulations

- ▶ Regulatory, But Not
- ▶ General Legal Considerations
- ▶ CMS Clinical Trial Policy
- ▶ PPACA
- ▶ PPACA vs. CMS
- ▶ Subject Injury
- ▶ Enforcement
- ▶ Conclusions

# Regulatory, But Not

- ▶ Overlap of FDA, CMS, PPACA, State Laws, etc.
- ▶ Clinical trials are just small piece of bigger picture of reimbursement, Medicare, insurance, etc.

# General Legal Considerations

- ▶ False Claims Act
- ▶ Anti-Kickback Statute
- ▶ Inducements
- ▶ Indigent Care

# Healthcare Billing

- ▶ Pressures on all involved in clinical research
  - ▶ All want to do the right thing
  - ▶ Rules are complex and ever-changing
  - ▶ Increasing numbers of clinical trial subjects are government healthcare beneficiaries
  - ▶ Enforcement and oversight of research institutions and billing practices are increasing
  - ▶ So....
  - ▶ CMS is watching closely (NCT#)



# False Claims Act

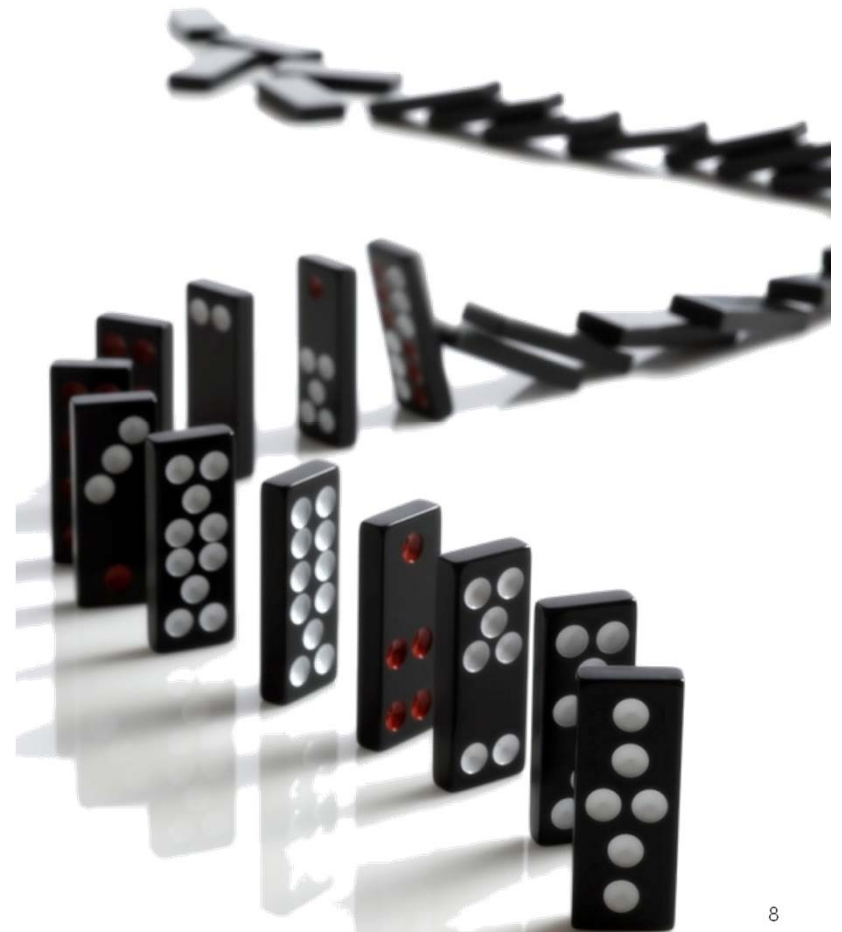
- ▶ False Claims Act (FCA):
  - ▶ Prohibits filing or causing the filing of false claims, or creating a false record to get a claim paid.
  - ▶ The core of a false claims case is that the government was cheated in one form or another – the “false claim.”
  - ▶ Typically occurs in research by double billing or improper or unnecessary billing.
- ▶ Between 1987 and 2008 the Government recovered nearly \$22 billion under the False Claims Act; over 6,200 qui tam FCA actions filed; \$2.2 billion to whistleblowers
- ▶ Enforcement has sky-rocketed: Between 2009 and 2014 the government recovered \$22.75 billion; in 2014 alone: 700 qui tam actions filed; \$435 million to whistleblowers

# Anti-Kickback Statute

- ▶ Anti-Kickback Statute (AKS):
  - ▶ Prohibits paying, offering to pay, or receiving payment in exchange for the referral of services or devices that are covered under a federal health care program.
- ▶ Kickback issues can arise in the following contexts:
  - ▶ Post-market/data registry studies
  - ▶ Waivers of co-payments and deductibles
  - ▶ Inducements for future purchases, referrals
  - ▶ Off-label promotions
  - ▶ Investigator promotions

# Potential Large-Scale Impact

- ▶ Even if the amount/situation seems small to you, remember:
  - ▶ The overall financial implications
  - ▶ No “de minimis” exceptions





## Potential Issue: Inducements

- ▶ Remuneration paid to subjects in clinical trials, whether direct (compensation) or through the waiver of cost-sharing responsibilities under private or public insurance, can be viewed as an inducement
- ▶ The Office of Inspector General takes very seriously the issue of inducements in clinical research:
  - ▶ “[M]any clinical trials...will study items and services for which there are effective, well-established treatments already available. In such cases, enrollees could well be induced to forgo equally effective or more appropriate care. . . . Payments to providers and participating patients potentially present a risk of fraud and abuse.”

From OIG Advisory Opinion No. 04-01:

<https://oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao0401G.pdf>

# Uninsured/Indigent Care

- ▶ Exception from the prohibition of “remuneration” paid to Medicare beneficiaries:
  - ▶ Non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determination of financial need or exhaustion of reasonable collection efforts (Section 1128A(a)(5) of the Social Security Act)
- ▶ “Nothing in the [CMS] regulations. . . prohibit[s] a hospital from waiving collection of charges to any patients, Medicare or non-Medicare, including low-income, uninsured or medically indigent individuals, if it is done as part of the hospital’s indigency policy.”
  - ▶ FAQ on Charges for the uninsured, available at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/downloads/FAQ\\_Uninsured.pdf](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/downloads/FAQ_Uninsured.pdf)

# Uninsured/Indigent Care

- ▶ Many institutions have defined indigency programs
  - ▶ Patients must meet criteria
  - ▶ Governed by applicable statutes, regulations, and hospital policies
- ▶ Note that these are hospital indigency programs, NOT sponsor administered programs
- ▶ If government views hospital as being responsible, but sponsor pays instead, consider implications . . .

# Clinical Trial Billing

- ▶ Common billing errors:
  - ▶ Billing for services not rendered
  - ▶ Billing Medicare (or other payers) for free items/services
  - ▶ Billing for non-reimbursable items/services (non qualifying or research driven)
  - ▶ Billing without proper codes, modifiers, NCT # or incorrect payer
  - ▶ Billing Medicare without approval for device studies
  - ▶ Waiving/paying /reimbursing subject co-pay and/or deductible obligations
  - ▶ Billing for items not supported by required documentation
    - ▶ proper order
    - ▶ documentation of medical necessity for the patient
    - ▶ documentation of study participation, as required

# CMS Clinical Trial Policy

- ▶ Evolution
- ▶ Qualifying Clinical Trials
- ▶ Routine Costs

# Evolution of CMS Rules

- ▶ 1995: IDE Category B Device Coverage
- ▶ 2000: First CMS Clinical Trial Policy (CTP) coverage available for devices/studies with NCDs
- ▶ 2005: Medicare Modernization Act (MMA) allows coverage of routine costs in qualifying IDE Category A Device Trials
- ▶ 2007: CMS attempted to change course; result was only slightly modified CTP
- ▶ 2010: MMSEA creates reporting requirements for clinical trial sponsors as primary payers where payment for research injuries
- ▶ 2013: New process and criteria for determination of coverage for IDE studies...
- ▶ 2015: These became effective Jan. 1.

# CMS – Qualifying Clinical Trial

- ▶ A “qualifying clinical trial” MUST meet the following three requirements:
  - ▶ The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (i.e., physicians’ service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids);
  - ▶ The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent; and
  - ▶ Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

# CMS – Qualifying Clinical Trial

- ▶ Trials should have these seven “desirable characteristics”:
  - ▶ The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
  - ▶ The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
  - ▶ The trial does not unjustifiably duplicate existing studies;
  - ▶ The trial design is appropriate to answer the research question being asked in the trial;
  - ▶ The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
  - ▶ The trial is in compliance with Federal regulations relating to the protection of human subjects; and
  - ▶ All aspects of the trial are conducted according to the appropriate standards of scientific integrity.



# CMS – Qualifying Clinical Trial

- ▶ “Deemed” Qualifying If: (one of the four)
  - ▶ Funded by NIH, CDC, AHRQ, CMS, DOD, or VA; or
  - ▶ Conducted under IND; or
  - ▶ IND-Exempt 21 C.F.R. 312.2(b)(1)); or
  - ▶ Supported by Centers/cooperative groups that are funded by NIH, CDC, AHRQ, CMS, DOD, or VA

# CMS CTP

- ▶ Ceiling
- ▶ Only “Qualifying Clinical Trials”
- ▶ Only “Routine Costs” Items/Services
- ▶ Coverage analysis

# CMS

- ▶ CMS CTP Routine Costs
- ▶ Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- ▶ Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- ▶ Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, in particular, for the diagnosis or treatment of complications.

# CMS Clinical Trial Policy

- ▶ “Routine Costs” do not include the following:
  - ▶ Items which are statutorily excluded or for which there is a non-coverage decision;
  - ▶ Investigational item or service itself, unless otherwise covered outside of the clinical trial;
  - ▶ Items and services used solely to meet data collection and analysis requirements (e.g., monthly CT scans for a condition usually requiring only a single scan); and
  - ▶ Items and services customarily provided free of charge by the sponsor
- ▶ Avoid one-off determinations: consider whether/when items/services become “customarily provided free of charge by the sponsor”

# CMS CTP – New IDE Study Process and Criteria

- ▶ CMS Final Rule to implement Calendar Year (CY) 2014 Physician Fee Schedule (PFS) included a revision to the Medicare regulations governing coverage for items and services provided in an IDE clinical study. 78 Fed. Reg. 74230.
- ▶ Began January 1, 2015, for IDE Studies:
  - ▶ Centralized CMS determination of Medicare coverage
  - ▶ New criteria for coverage
- ▶ Attempt to eliminate significant variability
- ▶ May make it harder to obtain coverage

# CMS CTP – New IDE Study Coverage Criteria

- ▶ The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
- ▶ The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- ▶ The study results are not anticipated to unjustifiably duplicate existing knowledge.
- ▶ The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.
- ▶ The study is sponsored by an organization or individual capable of successfully completing the study.
- ▶ The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.
- ▶ Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.
- ▶ The study is registered with the National Institutes of Health (NIH) National Library of Medicine's (NLM) ClinicalTrials.gov.
- ▶ The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.
- ▶ The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.



# PPACA VS. CMS

# PPACA

- ▶ Goal to have more people insured
- ▶ Floor (not ceiling)
- ▶ Only “Approved Clinical Trials”
- ▶ Only “Routine Patient Costs”



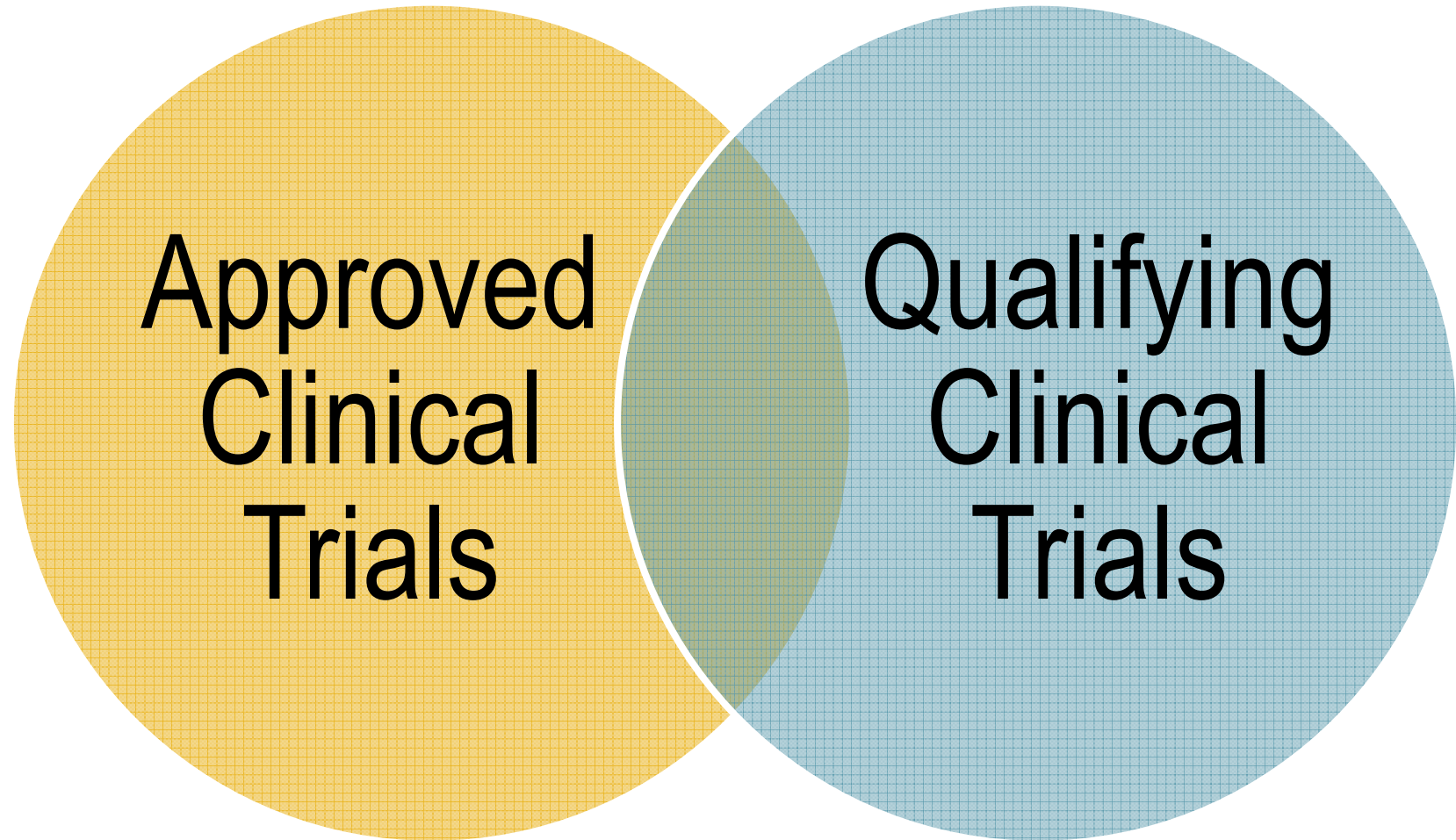
# PPACA Definition of “Approved Clinical Trials”

- ▶ In General. In this section, the term “approved clinical trial” means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening diseases or condition and is described in any of the following subparagraphs:
  - ▶ (A) Federally Funded Trials. The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:
    - ▶ (i) The National Institutes of Health.
    - ▶ (ii) The Centers for Disease Control and Prevention.
    - ▶ (iii) The Agency for Health Care Research and Quality.
    - ▶ (iv) The Centers for Medicare & Medicaid Services.
    - ▶ (v) Cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.
    - ▶ (vi) A qualified non-governmental research entity identified in the guidelines issues by the National Institutes of Health for center support grants.
    - ▶ (vii) Any of the following if the conditions described in paragraph (2) are met:
      - ▶ (I) The Department of Veterans Affairs.
      - ▶ (II) The Department of Defense.
      - ▶ (III) The Department of Energy.
  - ▶ (B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

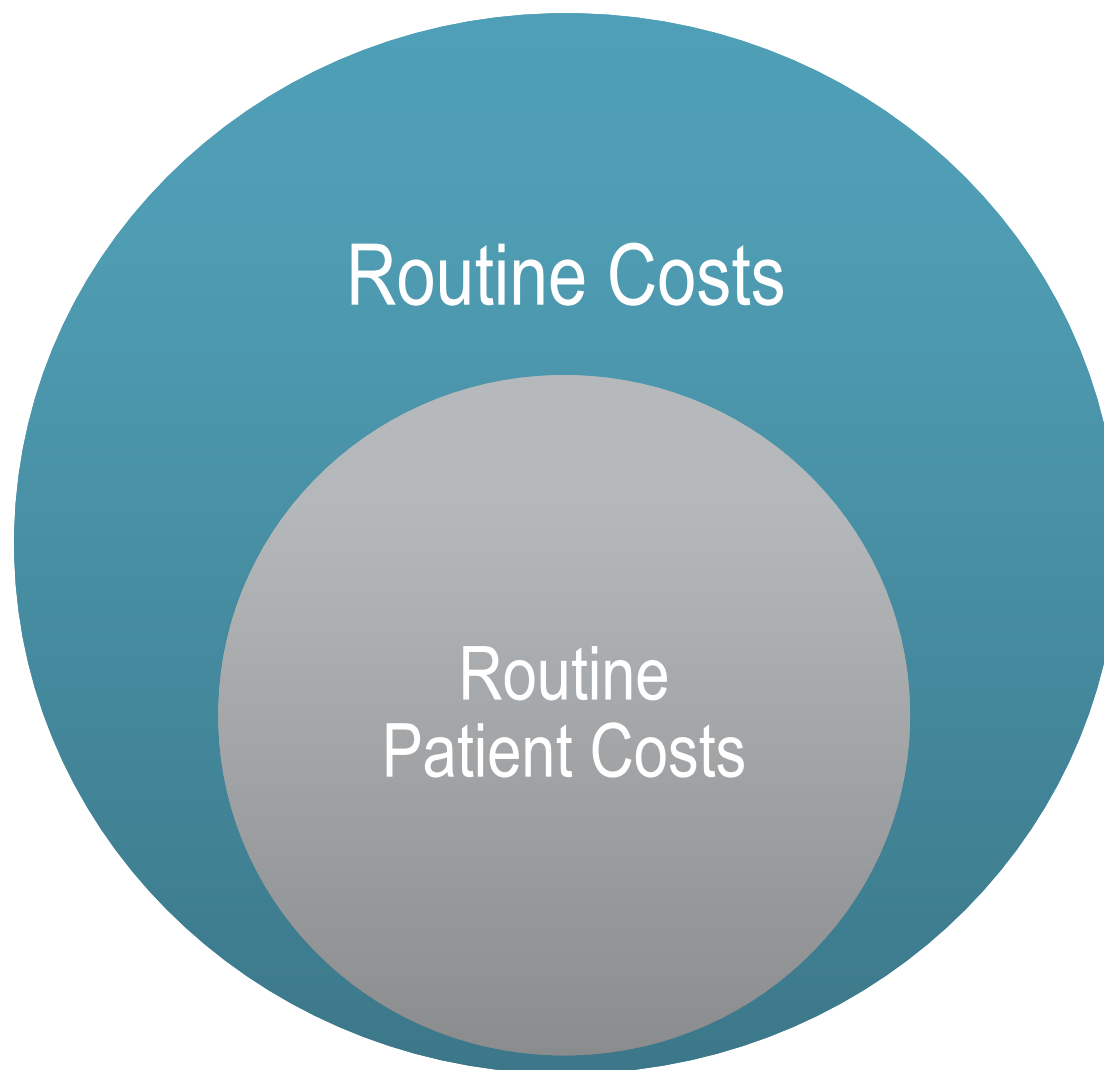
# PPACA

- ▶ PPACA “Routine Patient Costs”
  - ▶ “all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial”

# PPACA vs. CMS



# PPACA vs. CMS



# CMS Clinical Trial Policy

- ▶ Subject injury
- ▶ MSP
- ▶ MMSEA Reporting

# Medicare Secondary Payer

- ▶ Basic Rule – 42 C.F.R. § 411.32  
Medicare benefits are secondary to benefits payable by a primary payer even if State law or the primary payer states that its benefits are secondary to Medicare benefits or otherwise limits its payments to Medicare beneficiaries
- ▶ Application to Clinical Research -CMS has interpreted the promise to pay for research related injuries in many clinical trial agreements as triggering the MSP rule and thus prohibiting primary payment from Medicare

# Subject Injury Reimbursement

- ▶ Section 111 of Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA) added mandatory reporting requirements for trial sponsors who pay for research related injuries sustained by Medicare beneficiaries
- ▶ When payments are made by sponsors of clinical trials for complications or injuries arising out of the trials, such payments are considered to be payments by liability insurance (including self-insurance) and must be reported. The appropriate Responsible Reporting Entity (RRE) should report the date that the injury/complication first arose as the Date of Incident (DOI). The situation should also be reported as one involving Ongoing Responsibility for Medicals (ORM)
- ▶ Claims require inclusion of an 8-digit clinical trial number
- ▶ IRBs and AAHRPP have expectations regarding responsibility

# 2015 Requirements

- ▶ NGHP RREs should obtain, or must document their attempts to obtain, either the HICN/full SSN of participants, or, if it cannot obtain that, it may instead report to CMS:
  - ▶ Last five digits of SSN,
  - ▶ First initial,
  - ▶ Surname,
  - ▶ Date of birth, and
  - ▶ Gender



# Enforcement



# Institution Enforcement

- ▶ Institution enforcement and self-reporting on these issues continues to grow
- ▶ Also possibility that enforcement attention to industry brings scrutiny to industry-research
- ▶ Whistleblowers



## Example: Rush University Medical Center

- ▶ December 2005
- ▶ Among the first settlements related solely to the Medicare Clinical Trial Policy
- ▶ Improperly billed sponsor and Medicare for physician and hospital cancer research services that were not reimbursable as routine care costs in the CMS Clinical Trial Policy
- ▶ \$1 million settlement

## Example: University of Alabama at Birmingham

- ▶ April 2005
- ▶ Allegations:
  - ▶ Falsely billed Medicare for clinical research trials that were also billed to sponsor
  - ▶ Falsely billed Medicare for researcher's time spent on patient care when no patients had been seen
- ▶ \$3.39 million settlement

# Example: Tenet Healthcare and the Corporate Integrity Agreement

- ▶ 2006: \$900 million settlement to resolve claims of upcoding, kickbacks, and excessive outlier payments.
  - ▶ Signed a Corporate Integrity Agreement that led to two more settlements:
    - ▶ 2010: \$1.9 million to settle allegations against USC Norris Cancer Center that between 2003 and 2007 it improperly billed for:
      - ▶ “(1) items or services that were paid for by clinical research sponsors or grants under which the clinical research was conducted;
      - ▶ (2) items or services intended to be free of charge in the research informed consent;
      - ▶ (3) items or services that were for research purposes only and not for the clinical management of the patient; and/or
      - ▶ (4) items or services that were otherwise not covered under the ...(CMS) Clinical Trial Policy.”
    - ▶ 2012: \$42.75 million to settle allegations of overbilling Medicare for treatment at IRFs when the patients did not meet the standards for the specialized treatment between 2005 and 2007.
  - ▶ 2014: \$5 million to settle claims that Tenet leased property to doctors at low rates in exchange for referrals

# A Shot Across the Bow

- ▶ September 2012: HHS issued a letter warning five major hospital associations that their use of electronic medical records is being monitored closely in an effort to reduce overpayments and potential “gaming” of the system
- ▶ Lots of Medicare billing enforcement in 2012
  - ▶ High priority for government; close scrutiny of billing trends at institutions
- ▶ “[T]here are troubling indications that some providers are using this technology to game the system, possibly to obtain payments to which they are not entitled. False documentation of care is not just bad patient care; it's illegal. These indications include potential ‘cloning’ of medical records in order to inflate what providers get paid. There are also reports that some hospitals may be using electronic health records to facilitate ‘upcoding’ of the intensity of care or severity of patients' condition as a means to profit with no commensurate improvement in the quality of care.”

## Example: Emory University

- ▶ August 2013
- ▶ \$1.5 million settlement
- ▶ The United States and the State of Georgia alleged that Emory University billed Medicare and Medicaid for services the clinical trial sponsor agreed to pay and, in some cases, actually did pay, thereby resulting in Emory being paid twice for the same service.
- ▶ Complaint cites Emory's use of "dysfunctional, substandard clinical study accounting and control systems which defendants knew or were reckless in not knowing would result in submission of false claims."

# Other Billing Violation Enforcement

- ▶ Columbia University
  - ▶ October 2014: \$9 million FCA settlement
  - ▶ As a federal grant administrator, submitted false claims for research on HIV/AIDS that—as the complaint alleges— “Columbia was well aware that this was not being done, yet continued to charge many federal grants for work that as not devoted to the projects.”
- ▶ Northwestern University
  - ▶ July 2013: \$3 million FCA settlement
  - ▶ Cancer researcher submitted false claims under NIH research grants for unqualified services of his relatives as ‘consultants’ and for food, hotel and travel for himself and his family and friends.
- ▶ Cornell University
  - ▶ March 2009: \$2.6 million settlement to resolve FCA claims based on wrongful reporting in NIH grant applications
  - ▶ Claimed that researcher omitted information grant applications that “deprived the Government of its ability to assess the researcher’s ability to perform the projects and the amount of research time they plan to devote to each project.”



# Tips

- ▶ Recognize there is a significant continuum of sophistication on the part of sponsors and sites about:
  - A. existence and implications of CMS Clinical Trial Policy
  - B. identifying routine care
  - C. exclusions from definition of routine care
  - D. application of PPACA
- ▶ Many drug companies still just wading into learning what is possible in terms of third party reimbursement in clinical research. Many device companies got there sooner because of the availability of reimbursement for the devices.
- ▶ Recognize risky area where sites ultimately make submissions for reimbursement but sponsors have big part in drafting budgets and setting expectations. Recognize that there is enough liability to go around, not just one or the other.
- ▶ Policies, training and monitoring are imperative!

# Concluding Comments

- ▶ Complex and highly regulated area
- ▶ High stakes and high expectations
- ▶ Wide range of sophistication among all involved -- companies, researchers, etc.
- ▶ Sometimes expectations are counter-intuitive for lawyers
- ▶ Increasing transparency
- ▶ Increasing sophistication and resources of regulators and enforcers
- ▶ Basic moral compass
- ▶ Always remember to consider the interests and needs of the patient

## Coverage of Care in Device Studies– 42 C.F.R. § 405.207

Medicare payment may be made for:

- 1) Covered services to treat a condition or complication that arises due to the use of a noncovered device or a noncovered device-related service; or
- 2) Routine care services related to experimental/investigational (Category A) devices as defined in §405.201(b); and furnished in conjunction with an FDA-approved clinical trial. The trial must meet criteria established through the national coverage determination process; and if the trial is initiated before January 1, 2010, the device must be determined as intended for use in the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition.
- 3) Routine care services related to a non-experimental/investigational (Category B) device defined in §405.201(b) that is furnished in conjunction with an FDA-approved clinical trial

## Payment for Device Itself - 42 C.F.R. § 405.209

- ▶ Payment under Medicare for a non-experimental investigational (Category B) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared by the FDA.

# Issue Spotting

- ▶ “A patient arrives at a hospital for a physician-ordered x-ray. After the patient makes a vague reference to a clinical trial in which she is participating, the hospital double checks the order form to confirm it is performing the correct x-ray. The hospital later bills Medicare for the x-ray. After receiving Medicare reimbursement, the hospital receives a check from the physician group to pay for performing the x-ray because the x-ray was requested as part of a clinical trial sponsored by a medical device company. The physician group received payments from the medical device company to conduct the clinical trial.”

# Provider Self-Disclosure of Wrongful Billing

- ▶ Depending on the specific circumstances, there can be benefits to provider self-disclosure upon discovery of fraudulent activity
- ▶ OIG resolved 235 cases through self-disclosure between 2009-2013
- ▶ Strongly encouraged by OIG, which asserts that the benefits of self-disclosure include:
  - ▶ Serves as evidence “of a robust and effective compliance program” which creates “a presumption against requiring integrity agreement obligations in exchange for a release...”
  - ▶ Fact-dependent, but OIG “believe[s] that individuals or entities that use the [self-disclosure protocol] and cooperate with OIG during the...process deserve to pay a lower multiplier on single damages”
  - ▶ May mitigate potential exposure under 42 U.S.C. 1320(a)-7(k)(d)
  - ▶ OIG will attempt to process the issue more quickly
- ▶ There are specific requirements for false billing self-disclosures